



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0883]

Purdue Pharma L.P.; Withdrawal of Approval of a New Drug Application for Oxycontin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, held by Purdue Pharma L.P. (Purdue), One Stamford Forum, Stamford, CT 06901-3431. Purdue has voluntarily requested that approval of this application (NDA 20-553) be withdrawn and has waived its opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993-0002, 301-796-3522.

SUPPLEMENTARY INFORMATION: FDA approved NDA 20-553 for OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, 10 milligrams (mg), 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg, (original OxyContin), on December 12, 1995. A reformulated version of these products, OXYCONTIN (oxycodone hydrochloride) Extended-Release Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg (reformulated OxyContin), is the subject of NDA 22-272, also held by Purdue and initially approved on April 5, 2010. Reformulated OxyContin was developed with physicochemical properties that are

intended to make the tablet more difficult to manipulate for purposes of abuse or misuse. Both original and reformulated OxyContin are opioid agonist products. Original OxyContin was indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

In correspondence dated August 10, 2010, Purdue notified FDA that it had ceased shipment of original OxyContin, and FDA subsequently moved original OxyContin to the "Discontinued Drug Product List" section of the Orange Book. In a letter to FDA dated March 19, 2013, Purdue requested that FDA withdraw approval of NDA 20-553 for original OxyContin, noting that the original formulation of OxyContin was subject to abuse and misuse, and that it was "not possible to develop labeling or REMS provisions that would create a positive risk/benefit ratio for the original formulation of OxyContin." In that letter, Purdue waived its right to a hearing.

On April 18, 2013, FDA published notice of its determination that original OxyContin, NDA 20-553, was withdrawn from sale for reasons of safety or effectiveness (78 FR 23273). The notice concluded that "[o]riginal OxyContin ... poses an increased potential for abuse by certain routes of administration, when compared to reformulated OxyContin. Based on the totality of the data and information available to the Agency at this time, FDA concludes that the benefits of original OxyContin no longer outweigh its risks."

Under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 20-553, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without

an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 30, 2013.

Janet Woodcock,

Director,

Center for Drug Evaluation and Research.

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